Foregen

Preclinical Research Overview

Introduction

- Goal:
  - To complete the remaining preclinical objectives in preparation for human clinical trials.
- Milestones:
  - Collection of donor tissue
  - Dynamic decellularization
  - Dynamic recellularization
  - Bioreactor Maturation
- Estimated completion date:
  - Q4 2025

Foregen

Team

- Dr. Stanislav Žiaran, MD, PhD.
  - Comenius University - Bratislava, Slovakia
  - Urological surgeon
  - Distinguished researcher in regenerative medicine

Foregen

Team

- Ján Kováč
  - Comenius University - Bratislava, Slovakia
  - PhD candidate
  - Experience with bioreactors, 3D bioprinting, tissue engineering

Foregen

Milestones

Description	Start Date	Duration
Milestone I Collection of Donor Tissues and Samples	January 2nd, 2025	3 months
Milestone II Dynamic Decellularization	January 3rd, 2025	3 months
Milestone III Dynamic Recellularization	January 5th, 2025	4 months
Milestone IV Bioreactor Maturation	January 6th, 2025	6 months

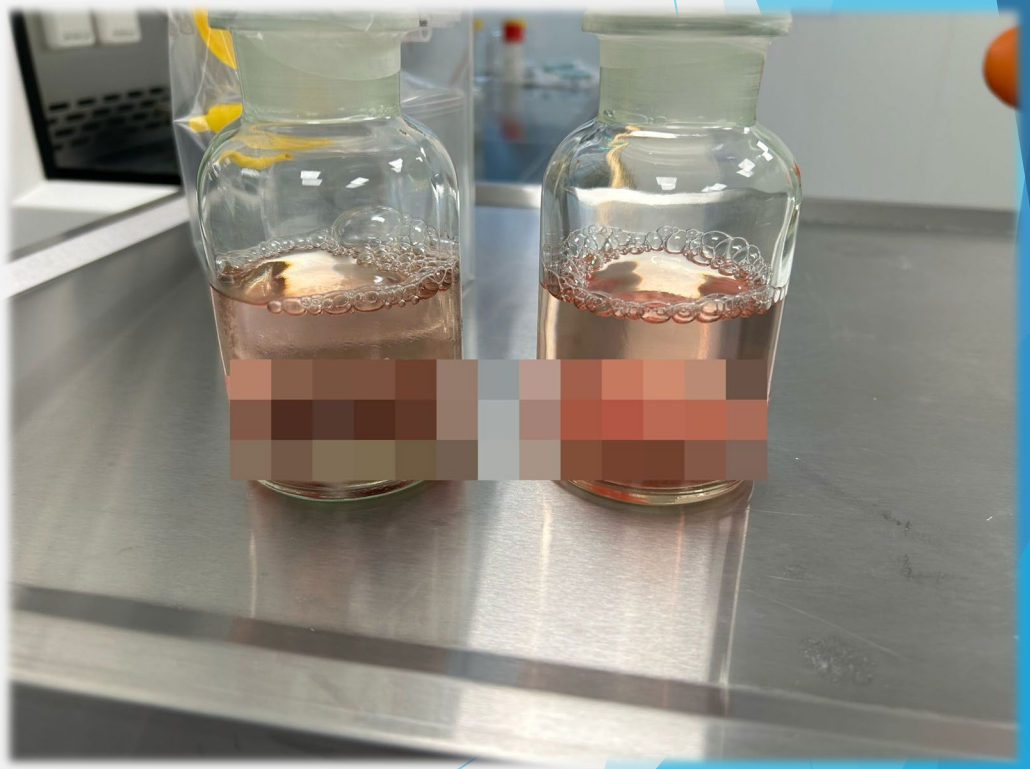
Done in parallel

Foregen

Milestone I: Collection of Donor Tissue

I. Main activities
   I. Define donor criteria and tissue collection methods.
   II. Determine storage and transport protocols.
   III. Develop and validate collection protocols.

II. Outcomes
   I. Validated protocols for tissue collection.
   II. Successfully collected and stored donor samples.
   III. Detailed database of samples.



Foregen

Milestone II: Dynamic Decellularization

I. Main activities
   I. Optimize decellularization techniques.
   II. Analyze tissue using histology, SEM, and biomechanics.
   III. Develop storage and transport protocols.

II. Outcomes
   I. Characterized decellularized tissue.
   II. Minimized variability across samples.

Foregen

Milestone III: Dynamic Recellularization

I. Main activities
   I. Optimize recellularization protocols using stem cells.
   II. Identify growth factors and visualization methods.
   III. Conduct detailed tissue analysis.

II. Outcomes
   I. Validated protocols for cell culture and differentiation.
   II. Characterized recellularized tissue.

Foregen

Milestone IV: Bioreactor Maturation Before Implantation

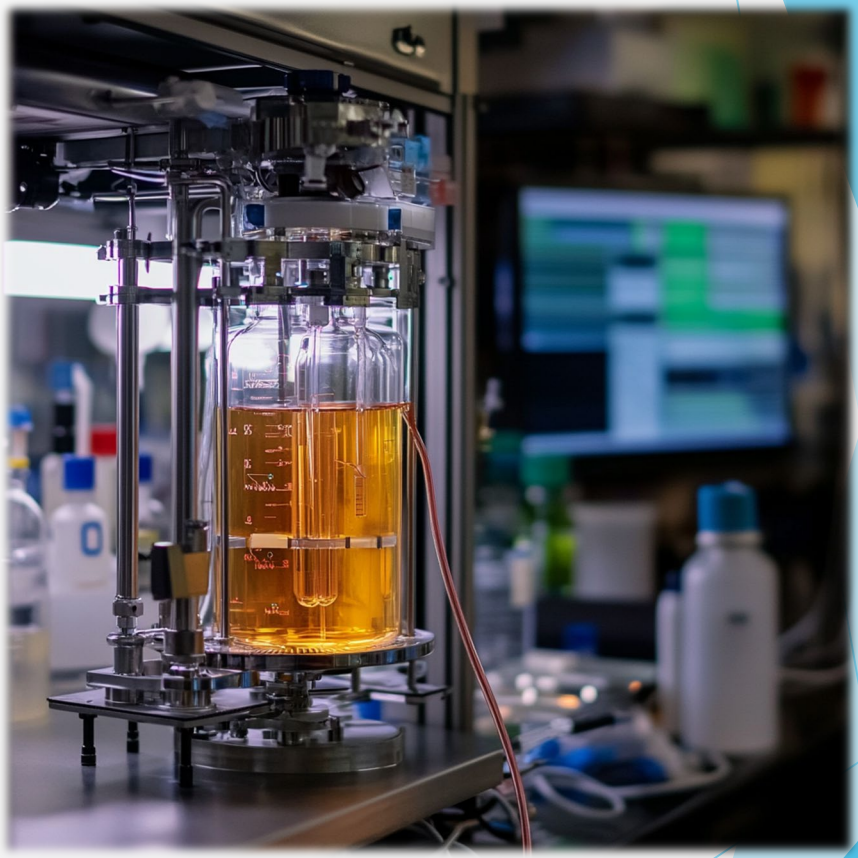
I. Main activities
   I. Optimize bioreactor components for tissue preparation.
   II. Develop methods for effective tissue maturation.
   III. Conduct final tissue analyses.

II. Outcomes
   I. Protocols for implant-ready tissue.
   II. Fully characterized tissue for clinical testing.

Foregen

Advantages of Bioreactor

- Eliminates 2-stage surgery
- Safer and quicker procedure
- More likely to be approved
- Tissue preparation more consistent



Foregen

Next Steps

- Finalize surgical plan
- Partner with Contract Research Organization (CRO)
- Create study design for human clinical trials
- Apply for ethics approval

Foregen

Thank you for your support

Foregen